

Experiment Number: 20725 - 03
Test Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/Wistar Han

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
2,3-Butanedione
CAS Number: 431-03-8

Date Report Requested: 01/26/2017
Time Report Requested: 09:33:26
First Dose M/F: 08/17/09 / 08/17/09
Lab: BNW

Custom Report - Nose SC Carcinoma or SC Papilloma

NTP Study Number: C20725
Lock Date: 10/11/2012
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.5.0.0_sfh
PWG Approval Date: 04/12/2016

Experiment Number: 20725 - 03
Test Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/Wistar Han

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
2,3-Butanedione
CAS Number: 431-03-8

Date Report Requested: 01/26/2017
Time Report Requested: 09:33:26
First Dose M/F: 08/17/09 / 08/17/09
Lab: BNW

HISTORICAL CONTROL STUDIES
From August 2016 report

SAME ROUTE

20601-03 -- Antimony trioxide (INHALATION AIR)
20515-03 -- Metal Working Fluids: CIMSTAR 3800 (INHALATION AIR)
20523-03 -- Metal Working Fluids: TRIM VX (INHALATION AIR)

ALL ROUTES

20601-03 -- Antimony trioxide (INHALATION AIR)
20203-03 -- Green Tea Extract (GAVAGE WATER)
20515-03 -- Metal Working Fluids: CIMSTAR 3800 (INHALATION AIR)
20523-03 -- Metal Working Fluids: TRIM VX (INHALATION AIR)
20209-03 -- Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)] (GAVAGE CORN OIL)
20320-03 -- Tetrabromobisphenol A (GAVAGE CORN OIL)

Experiment Number: 20725 - 03

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

2,3-Butanedione

CAS Number: 431-03-8

Date Report Requested: 01/26/2017

Time Report Requested: 09:33:26

First Dose M/F: 08/17/09 / 08/17/09

Lab: BNW

**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Nose

Experiment Number: 20725 - 03
Test Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/Wistar Han

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
2,3-Butanedione
CAS Number: 431-03-8

Date Report Requested: 01/26/2017
Time Report Requested: 09:33:26
First Dose M/F: 08/17/09 / 08/17/09
Lab: BNW

SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF 2,3-BUTANEDIONE

MALE RATS

Organ

Nose

FEMALE RATS

Organ

Nose

Morphology

Sq Cell Carcinoma or Sq Cell Papilloma

Morphology

Sq Cell Carcinoma or Sq Cell Papilloma

Experiment Number: 20725 - 03
 Test Type: CHRONIC
 Route: RESPIRATORY EXPOSURE WHOLE BODY
 Species/Strain: RATS/Wistar Han

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 2,3-Butanedione
 CAS Number: 431-03-8

Date Report Requested: 01/26/2017
 Time Report Requested: 09:33:26
 First Dose M/F: 08/17/09 / 08/17/09
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
Nose				
Sq Cell Carcinoma or Sq Cell Papilloma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/44.43	0/45.17	0/43.05	4/40.48
POLY-3 PERCENT (g)	0%	0%	0%	9.9%
TERMINAL (d)	0/36 (0%)	0/37 (0%)	0/33 (0%)	1/22 (5%)
FIRST INCIDENCE	---	---	---	589
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	0/299 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.002**	(e)	(e)	P=0.049*
POLY 1.5	P=0.002**	(e)	(e)	P=0.055
POLY 6	P=0.002**	(e)	(e)	P=0.041*
COCH-ARM / FISHERS	P=0.003**	(e)	(e)	P=0.059
MAX-ISO-POLY-3	P=0.003**	(e)	(e)	P=0.019*
HISTCONT SAME RTE	P=0.033*	(e)	(e)	P=0.037*
HISTCONT ALL RTES	P=0.005**	(e)	(e)	P=0.003**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=1.000			

Experiment Number: 20725 - 03
 Test Type: CHRONIC
 Route: RESPIRATORY EXPOSURE WHOLE BODY
 Species/Strain: RATS/Wistar Han

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 2,3-Butanedione
 CAS Number: 431-03-8

Date Report Requested: 01/26/2017
 Time Report Requested: 09:33:26
 First Dose M/F: 08/17/09 / 08/17/09
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
Nose				
Sq Cell Carcinoma or Sq Cell Papilloma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/43.58	0/43.03	0/40.02	3/43.53
POLY-3 PERCENT (g)	0%	0%	0%	6.9%
TERMINAL (d)	0/34 (0%)	0/31 (0%)	0/24 (0%)	2/30 (7%)
FIRST INCIDENCE	---	---	---	724
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	0/299 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.011*	(e)	(e)	P=0.118
POLY 1.5	P=0.011*	(e)	(e)	P=0.119
POLY 6	P=0.010**	(e)	(e)	P=0.116
COCH-ARM / FISHERS	P=0.012*	(e)	(e)	P=0.121
MAX-ISO-POLY-3	P=0.009**	(e)	(e)	P=0.038*
HISTCONT SAME RTE	P=0.031*	(e)	(e)	P=0.048*
HISTCONT ALL RTES	P=0.005**	(e)	(e)	P=0.004**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=1.000			

Experiment Number: 20725 - 03
Test Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/Wistar Han

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
2,3-Butanedione
CAS Number: 431-03-8

Date Report Requested: 01/26/2017
Time Report Requested: 09:33:26
First Dose M/F: 08/17/09 / 08/17/09
Lab: BNW

LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
- (b) Number of tumor-bearing animals/Poly-3 number
- (d) Observed incidence at terminal kill.
- (e) Value of statistic cannot be computed.
- (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
- (g) Poly-3 adjusted lifetime tumor incidence.
- (h) Historical Controls statistic is not calculated when the HC Poly-3 rate is higher than the Poly-3 rates for all dose groups.
- (n) No statistics are calculated if all dose groups have fewer than two tumors.
- (I) Interim sacrifice
- (T) Terminal sacrifice
- # Tumor rates based on numbers of animals necropsied.
- * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
- ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
- N Indicates a negative trend for all tests
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***